

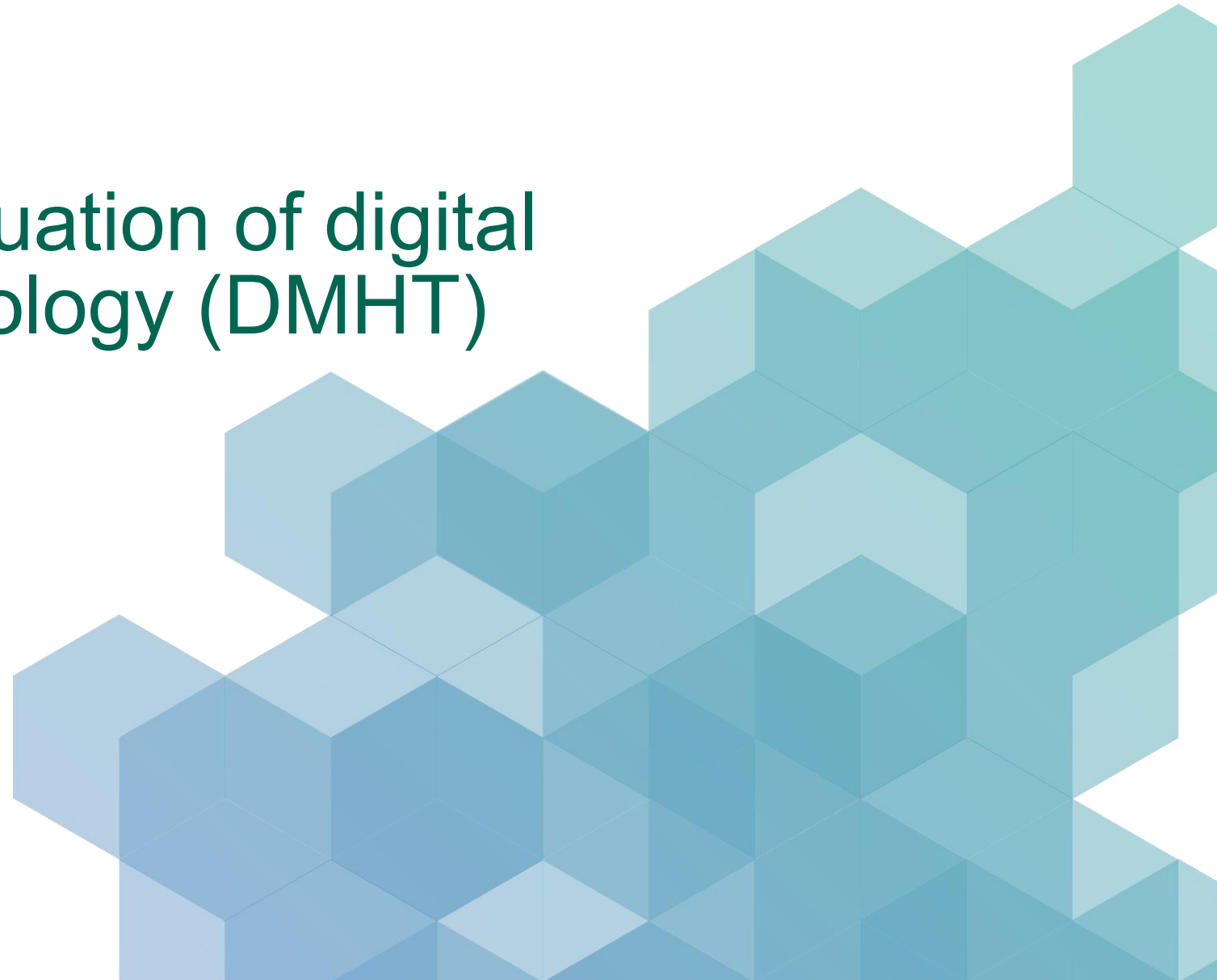


Medicines & Healthcare products
Regulatory Agency


Regulation and evaluation of digital mental health technology (DMHT)

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Medicines and Healthcare products Regulatory Agency (MHRA)

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18 August 2025 — Press release
[Parents and caregivers advised to stop all use of specific brand of kids' magnesium gummies due to the presence of an undeclared prescription-only medicine](#)
Parents and caregivers who have purchased Nutrition Ignition Kids Magnesium Glycinate Gummies



14 August 2025 — News story
[MHRA approves teplizumab to delay progression of type 1 diabetes](#)
As with any medicine, the MHRA will keep the safety and effectiveness of teplizumab under close review.



14 August 2025 — Open call for evidence
[Health Institution Exemption – Stakeholder survey](#)
The MHRA invites health institutions in Great Britain to share their experience of the health institution exemption (sometimes referred to as an in-house manufacturing exemption).

- An Executive Agency, sponsored by the **Department of Health and Social Care**.
- Regulate medicines, medical devices (including Software as a Medical Device (SaMD)) and blood components for transfusion in the UK.

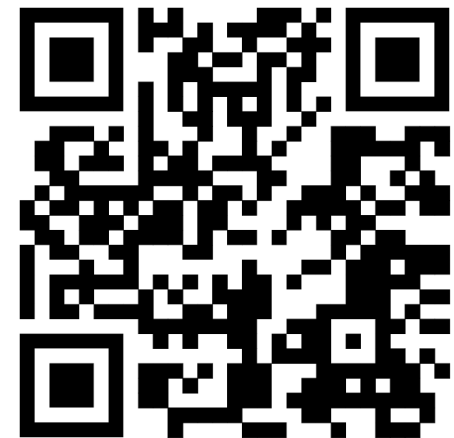
Wellcome-funded DMHT project

- **3-year project** from May 2023 to April 2026.
- **MHRA** and **NICE** are working collaboratively to clarify the **regulation** and **evaluation** of DMHTs.
- Engaging with a wide range of **stakeholders**:
 - Patients and the public
 - Healthcare professionals and researchers
 - Industry
 - Approved bodies and international regulators
 - Wider health ecosystem
- Overall goal to improve access to **acceptably safe** and **effective** DMHTs that support better **mental health outcomes**.

Collection

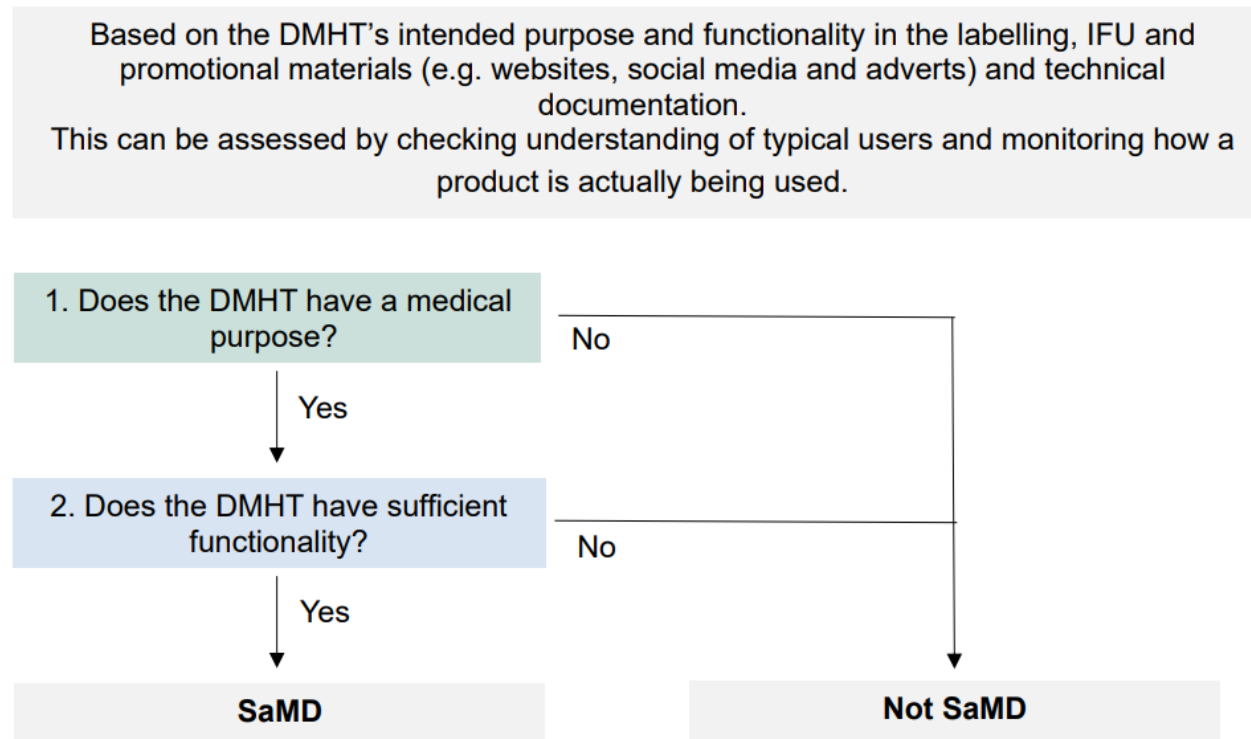
Digital mental health technology

The Wellcome Trust has funded a 3-year project focusing on effective regulation and evaluation of digital mental health technology.



MHRA guidance on DMHT: device characterisation, regulatory qualification & classification

Figure 2. Summary of process for determining DMHT qualification as SaMD.



XR example

What are the DMHT functionalities and computational tasks?			
What are the software inputs?	What are the computational tasks? How does the software process the inputs to get the outputs?	What are the software outputs?	Functionality?
Function 27 – Digital game			
Patient uses keyboard to move an avatar in a magical world where they come up against psychosocial challenges and have a wise owl to help guide them to develop CBT and DBT knowledge and skills.	E. Processes user instruction with an interactive and / or personalised output	Based on user's inputs, the game is played in different ways.	High
Function 28 – Virtual reality (VR) / augmented reality (AR) / mixed reality (MR)			
Healthcare professional chooses multiple options to create an interactive and personalised VR environment that will help patient with gradual exposure to feared situations and/or phobic stimuli in order to develop coping behaviours.	E. Processes user instruction with an interactive and / or personalised output	VR environment creation and VR environment adapts depending on patient's actions in VR environment.	High

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